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Award Number: **W81XWH-07-2-0118**

TITLE: **Early Support of Intracranial Perfusion**

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CONTRACTING ORGANIZATION:
University of Maryland, Baltimore
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REPORT DATE: **October 2009**

TYPE OF REPORT: **Annual Report**

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

X Approved for public release; distribution unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-10-2009	Annual	17 Sep 2008 – 16 Sep 2009

4. TITLE AND SUBTITLE
Early Support of Intracranial Perfusion

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-07-2-0118

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
University of Maryland, Baltimore
Baltimore, MD 21201

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Material Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This report represents the second year in a multi-year effort to improve outcomes in patients with traumatic brain injury (TBI). This project utilizes human and animal models in an effort first to identify what factors are important in determining outcome from TBI and secondly to test new techniques in patient care. Year 1 focused on development of an infrastructure for gathering data in TBI patients, development of a protocol to advance understanding of the inflammatory process which follows TBI, and creation of a basic science model of brain trauma. Staff were hired and assigned, equipment purchased and protocols and databases developed.
Year 2 has seen the implementation of two human use protocols, on-going development and testing of the Brain Resuscitation Registry (BRR) to provide structure and linkage capabilities for data collection and outcome reporting, and further development and re-formatting of the animal model sub-project. IRB protocols for year 3 projects are being developed for submission, equipment (server and computer tablets) purchased to allow the implementation of the BRR and assay kits ordered to allow the processing of specimens collected as part of the Cytokines sub-project. The basic science model was revised during Year 2 and now reflects both small and large animal models of polytrauma

15. SUBJECT TERMS
Traumatic Brain Injury (TBI); vital signs; cytokines; pre-hospital care; polytrauma

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON USAMRMC**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			**19b. TELEPHONE NUMBER** *(include area code)*
U	U	U	UU	34	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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INTRODUCTION

Traumatic Brain Injury (TBI) is the primary cause of trauma mortality in both civilian and military populations, a major source of long-term disability world-wide and a substantial independent cause of death in the U.S. The dominance of TBI in trauma epidemiology is due to our inability to treat primary central nervous system injury and the realization that the phenomenon of secondary brain injury (pathology at the metabolic, cellular, vascular and tissue levels) begins within seconds after the primary trauma and plays a profound role in the subsequent evolution of TBI.

The first phase of this multi-year effort to improve outcomes in TBI patients focused on developing the infrastructure necessary to associate elements of care for the TBI patient with specific and relevant outcomes, including establishment of a centralized Brain Resuscitation Registry for data capture, deployment of equipment to capture continuous pre-hospital and in-hospital vital signs, develop a protocol to examine the contribution of inflammatory cytokines after TBI and to develop an animal model of penetrating brain trauma.

During Year 2 the focus of work has been the implementation of two human use protocols, on-going infrastructure development and further development of the animal model sub-projects. The development of the Brain Resuscitation Registry, providing structure and linkage capabilities for human use data collection and outcome reporting, has moved into the beta testing phase. With purchase of a dedicated server and research computer tablets, full implementation of the system will begin early in Year 3.

BODY

This is the annual report for Year 2 of a multi-year project. Table 1 below reflects the Project Milestones Timeline adjusted based on the actual funding award date of September 17, 2007. Start and finish date columns reflect target timelines while subsequent columns reflect actual task completion dates. Research progress is further summarized by the itemized Statement of Work Tasks following the table.

Table 1: Timeline

Activity name	Target Completion		Actual Completion		
	State Date	Finish Date	2007+	2008	2009
Patient recruitment and monitoring					
**** IRB approvals**	1-Oct-07	31-Jan-08		Vital signs 02-Apr-08 Cytokines 29-Jul-08	
**** hiring and training of staff**	1-Oct-07	31-Jan-08			
****design and implementation of data collection systems**	1-Oct-07	31-Jan-08			
****patient enrollment**	31-Jan-08				
****data collection**	31-Jan-08				
****data collation and analysis**	1-May-08				
cytokine laboratory					
****identification and training of staff**	1-Oct-07				
****clinical data protocols**	1-Oct-07				
animal model					
****IRB approvals**	1-Oct-07			26-Feb-08	
****final study design**	1-Oct-07				

Implement plans for recruiting and monitoring patients.
Obtain Institutional Review Board (IRB) approval for recruiting and monitoring TBI patients.

Both human sub-projects have received IRB approval from the University of Maryland (UMB), IRB and the USAMRMC ORP, HRPO.

Sub-project 1: Vital Signs Data in Trauma Patients

This project was approved by UMB, IRB and USAMRMC ORP, HRPO upon continuing review on 2/21/08. This study was then re-assigned to the current project "Early Support of Intracranial Perfusion," on 2/26/08.

During Year 1 several amendments were made to the project including a waiver of informed consent. The annual renewal for this protocol was submitted to UMB IRB in December 2008 and approved for continuation on 1/19/09. The continuing review report was submitted to USAMRMC ORP, HRPO on 2/2/09 and the acceptance memorandum received on 2/27/09.

Sub-project 2: Early Support of Intracranial Perfusion – Cytokines

The protocol was initially submitted to UMB IRB on 3/20/08 and after requested revisions the final protocol was approved by UMB, IRB on 7/28/08 and USAMRMC ORP, HRPO on 7/29/08. The annual renewal for this protocol was submitted to UMB IRB on 2/27/09 and approved for continuation on 3/23/09. The continuing review report was submitted to USAMRMC ORP, HRPO on 4/17/09 and the acceptance memorandum received on 5/15/09.

New sub-projects for Year 3

At the close of Year 2, development was initiated on 2 new retrospective sub-projects to be completed in Year 3, in preparation for prospective studies. Both sub-projects are currently being developed and should be ready for submission to UMB IRB and USAMRMC HRPO during the first quarter of Year 3.

Traumatic Brain Injury and Fracture Fixation will retrospectively evaluate which factors may be predictive of beneficial vs. detrimental effect of early fracture fixation in patients with severe TBI.

Traumatic Brain Injury, Oxygenation and Outcomes will evaluate whether high vs. low supplemental oxygen administration is either beneficial or detrimental in terms of neurologic outcome in patients with severe TBI.

Complete the Brain Resuscitation Registry network architecture

During Year 1, a secure web-based Trauma Registry containing clinical patient information for trauma patients was established. Year 2 has focused on the continuing development of the network architecture. Links have been established to specialized clinical systems to automate the extraction of patient data needed to profile, enroll, manage and analyze current study populations. Security has been enhanced to restrict subject record access based on a user's job responsibilities and study privileges. Study protocols have been centralized and automated allowing for communication between studies to be established. Screens have been added to the Registry for current trauma patients to allow them to be selected for a study and then manage the abstraction of the subject's clinical data. The Cytokines sub-project has served as the test study for these processes and training of research staff has been initiated. Application

enhancements have been developed to allow for enrollment of study subjects at the bedside. This module, currently in beta testing, will provide a real-time census of current study subjects. Standard reporting is being developed for study management. A help feature continues to evolve to provide research staff with an on-line tutorial for application use and the processes behind the applications. Tools to evaluate and correct data quality issues such as missing or incorrect subject information continue to be developed and standardized definitions for data elements articulated. Ad-hoc reporting and data extraction tools are being identified to improve the analysis of study subject data. Purchase of a dedicated server and screening tablets was completed in the 4th quarter of Year 2. Policies and procedures will be finalized in early Year 3 with implementation of the application to follow.

Provide staffing and facilities to monitor patients and collect designated specimens

Sub-project 1: Vital Signs (VS) Data in Trauma Patients

Pre-hospital Vital Signs Data Collection (VSDC) system

During Year 1 emphasis was placed on the development of equipment and working with pre-hospital providers to expand capabilities to obtain pre-hospital vital signs data.

The course of Year 2 has been focused on further developed the pre-hospital VS analysis to allow auto cleaning of VS artifacts. Critical episodes of hypoxia (SpO2 <95%, <90% <75%, hypotension (SBP<90; <100 mmHg) and tachycardia (HR>120, >110,>100 bpm) were identified. All pre-hospital cases were linked with trauma registry data for identification of outcomes such mortality, hospital /ICU length of stay, admit and discharge GCS, brain injury status (AIS-head), ISS, etc. In addition, review of the medical record has been completed to identify pre-hospital LSI (life saving interventions) and during the in-hospital first 4 hour emergency LSI. Several high resolution VS based prediction models were developed to predict pre and in hospital LSI with Receiver Operator Curve (ROC) of 0.8 (See attached abstract).

In-hospital Vital Signs Data Collection (VSDC) system and Shock Trauma Physiological (STP) Registry has been upgraded

A limited system for vital signs data collection was in existence prior to the reassignment of this sub-project to the larger study, emphasis in Year 1 was on system upgrades and expansion of VSDC capabilities. Expansion of the VSDC system from initial location in the Trauma Resuscitation Unit (12 admission bays and 6 operating bays) to a total of 54 critical care bays/beds occurred during Year 1. Data mining was initiated and preliminary algorithms developed.

During Year 2 the VSDC system was further developed. Due to the low return on consents able to be obtained for subject participation, an amendment for a waiver of consent was submitted and approved by both UMB and USAMRMC. VSDC has been extended to cover all 90 patient beds in the entire shock trauma center (12-TRU, 6-OR, 36-ICU, 36-IMC). It is thought that this is the first time high resolution (every 6 seconds) patient physiological data are available in a real-time trauma patient research registry for an entire hospital (trauma center). Real time Shock Trauma Physiological (STP) Registry was developed to capture and archive real-time physiological data; process the collected physiological data and identify critical episodes of hypoxia, hypotension, tachycardia, intracranial pressure/cerebral perfusion pressure (ICP/CPP) hypotension and associated vital signs variability at 5 min/30 min/ 60 min intervals. The SPT is linked with the Brain

Resuscitation Registry (BRR) for patient outcomes. Emergency Trauma Resuscitation Unit (TRU) intubation and ICP monitored in intensive care unit traumatic brain injured patients were used to validate the reliability of STP registry and to develop the models to identify relationships between secondary brain injury and outcome.

Sub-project 2: Early Support of Intracranial Perfusion – Cytokines

Much of Year 1 focused on the standardization of policies and procedures for recruitment, specimen and data collection. The sub-project coordinator was assigned and identified research staff trained on recruitment and specimen/data collection procedures. Screening for this sub-project was opened on 8/20/08.

At the close of Year 2, 42 subjects had been enrolled in the study, with one screen-fail and one subject withdrawn. Eight of the 42 subjects ultimately expired due to their injuries. Of those remaining subjects, 27 have completed their 3 month follow-up, 14 have completed their 6 month follow-up, and 2 have completed their 12 month follow-up. On only two occasions were follow-ups unable to be completed despite multiple attempts to contact the subjects.

Preliminary analysis has focused on the first 30 cytokines subjects to study the relationship between the continuous patient VS (ICP, CPP, SBP, HR Variability and Pause Pressure Variability) and outcome (Mortality, hospital length of stay, surgical management, 3 Month and 6 Month GOSE). Critical episodes and dose of above or below VS limits were further calculated for the outcome prediction modeling. A total of 150 days of detailed VS data were available for prediction model development. Findings are further described in the Key Research Accomplishment section and appendix

Sub-project 3: Animal Model of Brain Injury

During Year 2, Dr Courtney Robertson, Co-investigator for the animal sub-projects left the University of Maryland. Her work on these protocols will be continued by Co-Investigators Dr. Gary Fiskum and Dr. Robert Rosenthal, who have been integrally involved with the sub-project since its inception.

Implement laboratory evaluation of inflammatory cytokines
Provide staffing, equipment, facilities and training to process study cytokine specimens

Sub-project 2: Early Support of Intracranial Perfusion – Cytokines

Standardization of procedures for handling of specimens collected and specimen storage was completed during the fourth quarter of Year 1. A technician was assigned to assist with specimen processing.

At the close of Year 2 sufficient assay materials required for processing the first 30 study subjects were ordered. Processing and analysis for these subjects is anticipated for the first quarter of Year 3.

Develop an animal model of brain injury
Coordinate with MRMC research institutions to develop this model

Sub-project 3: Animal Models of Brain Injury

The animal use protocol described in the initial statement of work was approved by the UMB IACUC on 9/21/07. It was subsequently submitted to the USAMRMC Animal Care and Use Review Office (ACURO) on 11/27/07. In response to the review by the USAMRMC ACURO, a revised protocol was submitted on 2/25/08 and approved by USAMRMC ACURO on 2/26/08.

Preliminary experiments were performed with antibodies to different markers of inflammation and oxidative stress to determine their suitability for application to both animal models of traumatic brain injury and to serum samples obtained from traumatic brain injury patients.

During the course of year 2, the model was changed to a large and small animal polytrauma model of contusional brain injury (controlled cortical impact) plus hemorrhagic shock. This change was necessary due to challenges in finding a vendor for the device necessary for conducting the penetrating brain injury paradigm with large animals, and feedback from the review of the last annual report that a large animal model of polytrauma caused by TBI plus hemorrhagic shock would be more clinically translational than that of a rodent model. A revised SOW was developed using a combination of both controlled cortical impact plus hemorrhagic shock with adult male Sprague Dawley rats and with adult male Hanford miniature swine (Sinclair Bio-resources). The manufacturer of a controlled cortical impact device suitable for mini-pigs was identified, and the equipment will soon be ordered and should arrive by January 1, 2010. We obtained University of Maryland animal care and use committee approval for the rat polytrauma model, and will now submit this protocol to the USAMRMC ACURO for approval. We received UMB approval in August, 2009 for the protocol with pigs and will be submitting to ACURO in the near future. Preliminary experiments performed with human cerebrospinal fluid samples indicate that they can be used in a new and novel assay that detects toxicity of these samples on culture cell lines, using cellular respiration and glycolysis as outcome measures.

KEY RESEARCH ACCOMPLISHMENTS

Sub-project 1: Vital Signs Data in Trauma Patients

At the close of Year 1

- Enhanced the pre-flight patient Vital Signs data collection network
- Developed and expanded the in-trauma center VS data collection network to cover all critical care bays (TRU, OR, ICU)
- Developed and deployed a total pre and in-hospital VS data collection network
- Developed a basic VS data mining system to collect, process, and predict patient outcomes
- Established a road map for innovative prediction algorithm development

At the close of Year 2

- Completed the hospital/center based real-time patient physiological data collection network (covers all 90 trauma center beds)
- Developed a basic Real time Shock Trauma Physiological (STP) Registry.

  Key research findings include:
    - Continuous Pre-Hospital VS reviewed by 3 Subject Matter Experts (SME) identified more critical episodes (up to 300%) than Trauma Registry (TR).N=177
    - SME identified critical episodes (HR>120 bpm, SpO2<90, SBP<90mmHg) predicted outcome (Mortality, LOS, d/c GCS) better than TR. N=177.
    - Continuous Pre-Hospital VS better predicted emergency life saving interventions (LSI) than TR (N=177)
    - EMS Pre-Hospital Protocols may be monitored remotely in pre hospital care of Traumatic Brain Injury (TBI). (N=64)
- Detail findings are described in the attached abstracts. Also see the detail VS based study in Cytokines sub project findings.

Sub-project 2: Early Support of Intracranial Perfusion – Cytokines

At the close of Year 2

- Recruitment of 42 study subjects

  30 cytokines cases were used to study the relationship between the continuous patient VS (ICP, CPP, SBP, HR Variability and Pause Pressure Variability) and outcome TBI patient outcome (Mortality, hospital length of stay, time of craniotomy, 3 Month and 6 Month GOSE).

  The findings are
    - ICU ICP>20, 30 CPP<50<60 predicts patient outcome better than patient charts VS.
    - Combined ICP>20 and CPP<60 episodes predict outcome better than individual ICP and CPP.
    - Pressure-time dose of automated ICP and CPP data predicts outcomes in severe TBI.
    - CPP/ICP Dose Index: Dynamic 3-D Scoring in the Assessment of TBI
    - Computerized patient vital signs charting method enhances real-time record keeping in ICU
    - Heart Rate Variability Is Associated With Intractable Intracranial Hypertension And Cerebral Hypoperfusion

  Detailed findings are described in the attached abstracts.

Sub-project 3: Animal Model of Brain Injury

At the close of Year 2

- A rat polytrauma model consisting of controlled cortical impact traumatic brain injury plus hemorrhagic shock has been successfully developed.
- Preliminary experiments performed with human cerebrospinal fluid samples indicate that they can be used in a new and novel assay that detects toxicity of these samples on culture cell lines, using cellular respiration and glycolysis as outcome measures

REPORTABLE OUTCOMES

a) Presentations:

16th World Congress of Disaster and Emergency Medicine (May 12-16 2009) Victoria, BC, Canada

Continuous Vital Signs acquisition improves prehospital trauma triage
Sen A, Hu P, Mackenzie C, Jordan S, Xiao Y, Dutton R, Scalea T

In-flight Vital Signs Blackbox for Trauma Care
Peter Hu, Colin Mackenzie, Richard Dutton, Ayan Sen, Yan Xiao, Douglas Floccare, Thomas Scalea.

Video technologies in emergency health research in assessing quality of care: a study of trauma resuscitation milestones
Sen A, Hu P, Mackenzie C, Xiao Y, Dutton R

American Telemedicine Association Conference, (April 26-29, 2009) Las Vegas, NV

Automated vital-sign recording identifies more critical episodes than chart abstraction
Peter Hu MS, CNE, Ayan Sen MD, Colin Mackenzie MD, FRCA, Yan, Xiao PhD, Sean Jordan EMT-B, Richard Dutton MD, MBA, Thomas Scalea, MD and Trauma Vital Signs Research Group (TVSG)

Can EMS Protocols be monitored remotely in pre hospital care of Traumatic Brain Injury (TBI)?
Colin Mackenzie MD, FRCA, Peter Hu MS, CNE Ayan Sen MD, Yan, Xiao PhD, Sean Jordan EMT-B, Richard Dutton MD, MBA, Thomas Scalea, MD.
Presented at the American Medical Informatics Association Annual Symposium (November 8-12, 2008) Washington DC

Automatic Pre-Hospital Vital Signs Waveform and Trend Data Capture Fills Quality Management, Triage and Outcome Prediction Gaps (Oral presentation)
Colin F Mackenzie MB ChB, FRCA, FCCM, Peter Hu MS CNE, Ayan Sen MD, Rick Dutton MD, Steve Seebode BS, Doug Floccare MD, MPH ,Tom Scalea MD

Statewide Real-Time In-Flight Trauma Patient Vital Signs Collection System (Poster)
Peter Hu, MS, CNE, Colin Mackenzie, MD, Richard Dutton, MD, Ayan, Sen, MD, Yan, Xiao PhD, Christopher Handley, MS, EMT-P, Danny Ho MS, Thomas Scalea, MD

American Society of Anesthesiologists Annual Conference (October 18-22, 2008) Orlando, FL.

Continuous prehospital vital signs record identifies increased abnormalities/predicts interventions.
Ayan Sen MD, Peter Hu MS, CNE, Colin Mackenzie MD, FRCA, Sean Jordan EMT-B, Richard Dutton MD, MBA. Program in Trauma,

American Telemedicine Association Annual meeting (April 6-9, 2008) Seattle, WA.

Challenges in developing real-time in-flight patient vital-signs data collection system
Peter Hu MS CNE, Christopher Handley MS EMT-P, Steve Seebode, Anne Conway RN MS, Ryan Gens BA, Colin Mackenzie MD, Danny Ho MS, Gregory Defouw MSCS, Phil Davies MS, Douglas Floccare[4] MD MPH

Real-time Patient Vital Sign Data Collection Network for Trauma Care
Peter F. Hu MS CNE, Colin Mackenzie MD, Richard P. Dutton MD, Grant Bochicchio MD, Kelly Bochicchio RN,MS, Yan Xiao PhD, John Spearman MBA, Thomas Scalea MD.
Presented at the 5th Annual Innovations in the Surgical Environment Conference, (June 26-27 2008) Baltimore, Maryland.

Lesson Learned: Developing In-Flight Patient Vital-Signs Data Collection Network
Peter Hu MS CNE, Christopher Handley MS EMT-P, Ayan Sen MD, Steve Seebode, Anne Conway RN MS, Ryan Gens BA, Betsy Kramer RN, Sean Jordan MHS, EMT-B, Rebecca Webb BA, CCRC, Gregory Defouw MSCS, Phil Davies MS, Danny Ho MS, Yan, Xiao PhD, Colin Mackenzie MD, and Trauma Vital Signs Investigator and Associates (TVSI,TVSRA) Group

Can Pre-Hospital Patient VS Predict Injury and Intervention?
Peter F. Hu MS CNE, Colin Mackenzie MD, Richard P. Dutton MD, Ayan Sen, MD, Douglas Floccare MD, MPH , Grant Bochicchio MD,MPH, Yan Xiao PhD, John Spearman MBA, Thomas Scalea MD.

b) Accepted for presentation:

American Association for the Surgery of Trauma AAST 2009 Annual Meeting
(October 1-3, 2009) Pittsburgh, PA

Pressure-time dose of automated ICP and CPP data predicts outcomes in severe TBI
Sibel Kahraman, MD, Peter Hu, MS, CNE, Yan Xiao, PhD, Richard P Dutton, MD, Bizhan Aarabi, MD, Deborah M Stein, MD, Thomas M Scalea, MD

American Society of Anesthesiologists ASA2009 Annual Meeting (October 17-21, 2009) New Orleans, LA

Real-time patient Vital Signs Data Registry for Trauma Patient Care
Richard Dutton MD, Peter Hu MS, CNE, Yan Xiao PhD, Dale Yeatts MD, Colin Mackenzie MD

High resolution ICP and CPP data better predict outcome of severe TBI
Richard P Dutton, M.D., M.B.A., Sibel Kahraman, M.D., Peter Hu, M.S., Yan Xiao, Ph.D. and Thomas Scalea, M.D.

c) Publications (Journal or Proceedings):

Mackenzie CF, Hu P, Sen A, Dutton R, Seebode S, Floccare D, Scalea T. **Automatic pre-hospital vital signs waveform and trend data capture fills quality management, triage and outcome prediction gaps.** AMIA Annu Symp Proc. Nov 6:318-22. 2008

Hu PF, Handley C, Seebode S, Conway A, Gens Y, Mackenzie C, Ho D, Defouw G, Davies P, Floccare D. **Challenges in Developing Real-Time In-Flight Patient Vital-Signs Data Collection System**. Telemedicine and e-Health. 14(1)105. 2008

Hu PF, Mackenzie CF, Dutton R, Bochicchio GV, Bochicchio K, Xiao Y, Spearman J, Scalea T. **Real-time Patient Vital Sign Data Collection Network for Trauma Care** . Telemedicine and e-Health. 14(1)62. 2008

Hu P, Handley C, Sen A, Seebode S, Conway A, Gens R, Kramer B, Jordan S, Webb R, Defouw G, Davies P, Ho D, Xiao Y, Mackenzie C **Lesson Learned: Developing In-Flight Patient Vital-Signs Data Collection Network** Proceedings of 5th Annual Innovations in the Surgical Environment Conference. 2008

Hu PF, Mackenzie C, Dutton RP, Sen A, Floccare D, Bochicchio G, Xiao Y, Spearman J, Scalea T. **Can Pre-Hospital Patient VS Predict Injury and Intervention?** Proceedings of 5th Annual Innovations in the Surgical Environment Conference. 2008

CONCLUSIONS

At the conclusion of Year 2 significant progress has been made toward meeting overall project milestones. The infrastructure of staff, technology and data management to support the completion of sub-projects and long-term assessment of TBI patients had been created. The robust Brain Resuscitation Registry (BRR) needed to accomplish the goals of this-multi year project continues to develop and be tested in the context of sub-project 2. Finalization of policies and procedures for the BRR will be completed in the half of Year 3, along with implementation of the screening and complete data capture for sub-project 2. Recruitment and data collection for the two human sub-projects is ongoing and preliminary data analysis has begun. Sub-project 2 is nearing the end of the recruitment phase and complete analysis of data will be a focus for Year 3. Revisions to the animal sub-project have been completed and activity will begin once all approvals are completed in early Year 3. Additional projects identified for completion in Year 3 are currently under development.

REFERENCES

Year 2

Literature searches were conducted during Year 2 as part of the ongoing Cytokines sub-project, pre-hospital TBI component of the Vital Signs sub-project and in preparation for 2 retrospective sub-projects.

References identified related to the Pre-hospital TBI management component of Vital Signs included:

Davis DP. Early ventilation in traumatic brain injury. *Resuscitation.* 2008 Mar; 76(3):333-40.

Warner KJ, Cuschieri J, Copass MK, Jurkovich GJ, Bulger EM. Emergency Department Ventilation Effects Outcome in Severe Traumatic Brain Injury. *J Trauma.* 2008;64:341–347

Minardi J, Crocco TJ. Management of Traumatic Brain Injury: First Link in Chain of Survival *Mount Sinai Journal of Medicine* 76:138–144, 2009

Stiver SI, Manley GT. Prehospital management of traumatic brain injury. *Neurosurg Focus* 25 (4):E5, 2008

Zebrack M, Dandoy C, Hansen K, Scaife E, Mann C, Bratton SL.. Early Resuscitation of Children With Moderate-to-Severe Traumatic Brain Injury. *Pediatrics* 2009;124:56–64

Key words/ topics utilized for the TBI and FiO2 study included: traumatic brain injury, FiO2, outcomes. The following references were identified:

Chang BS et al. Physiologic and functional outcome correlates of brain tissue hypoxia in traumatic brain injury. Crit Care Med 2009 vol 37;1 p.283 2.

Diringer MN et al. Hyperoxia - good or bad for the injured brain? Curr OPin Crit Care 2008. 14(2):167-171

Rosenthal G et al. The role of lung function in brain tissue oxygenation following traumatic brain injury. J. Neurosurg. 2008. 108:59-65

Key words/ topics utilized for the TBI and femur fracture study included: traumatic brain injury, femur fracture, outcomes. The following references were identified:

Scalea TM. Optimal Timing of Fracture Fixation: have we learned anything in the past 20 years?. J Trauma 2008;65:253-260

Anglen JO et al. The effect of femoral nailing on cerebral perfusion pressure in head-injured patients. J Trauma 2003;54:1166-1170

Giannoudis PV et al. When should we operate on major fracture in patients with severe head injuries? Am Jour Surg 2002;183:261-267.

Key words/ topics utilized for the Cytokine sub-project included: treatment intensity in traumatic brain injury and medication use in traumatic brain injury in ICU. Pertinent reference articles identified include:

Ahmed, N., Bialowas, C., Kuo, Y. H., & Zawodniak, L. (2009). Impact of preinjury anticoagulation in patients with traumatic brain injury. *Southern Medical Journal, 102*(5), 476-480.

Cifu, D. X., Kreutzer, J. S., Kolakowsky-Hayner, S. A., Marwitz, J. H., & Englander, J. (2003). The relationship between therapy intensity and rehabilitative outcomes after traumatic brain injury: A multicenter analysis. *Archives of Physical Medicine and Rehabilitation, 84*(10), 1441-1448.

Cremer, O. L., van Dijk, G. W., van Wensen, E., Brekelmans, G. J., Moons, K. G., Leenen, L. P., et al. (2005). Effect of intracranial pressure monitoring and targeted intensive care on functional outcome after severe head injury. *Critical Care Medicine, 33*(10), 2207-2213.

Dohi, K., Satoh, K., Mihara, Y., Nakamura, S., Miyake, Y., Ohtaki, H., et al. (2006). Alkoxyl radical-scavenging activity of edaravone in patients with traumatic brain injury. *Journal of Neurotrauma, 23*(11), 1591-1599. doi:10.1089/neu.2006.23.1591

Franceschi, F., Marini, M., Ursella, S., Carbone, L., Candelli, M., Pignataro, G., et al. (2008). Use of oxycodone in polytrauma patients: The "gemelli" experience. *European Review for Medical and Pharmacological Sciences, 12*(2), 123-126.

Kadyan, V., Mysiw, W. J., Bogner, J. A., Corrigan, J. D., Fugate, L. P., & Clinchot, D. M. (2004). Gender differences in agitation after traumatic brain injury. *American Journal of Physical Medicine & Rehabilitation / Association of Academic Physiatrists, 83*(10), 747-752.

Lippert-Gruner, M., Lefering, R., & Svestkova, O. (2007). Functional outcome at 1 vs. 2 years after severe traumatic brain injury. *Brain Injury : [BI], 21*(10), 1001-1005.

Mrlian, A., Smrcka, M., & Klabusay, M. (2007). The importance of immune system disorders related to the Glasgow outcome score in patients after severe brain injury. *Bratislavske Lekarske Listy, 108*(8), 329-334.

Narotam, P. K., Burjonrappa, S. C., Raynor, S. C., Rao, M., & Taylon, C. (2006). Cerebral oxygenation in major pediatric trauma: Its relevance to trauma severity and outcome. *Journal of Pediatric Surgery, 41*(3), 505-513.

Neumann, M., Wang, Y., Kim, S., Hong, S. M., Jeng, L., Bilgen, M., et al. (2009). Assessing gait impairment following experimental traumatic brain injury in mice. *Journal of Neuroscience Methods, 176*(1), 34-44.

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APPENDICES

Abstracts Accepted or Presented:

Pressure-time dose of automated ICP and CPP data predicts outcomes in severe TBI

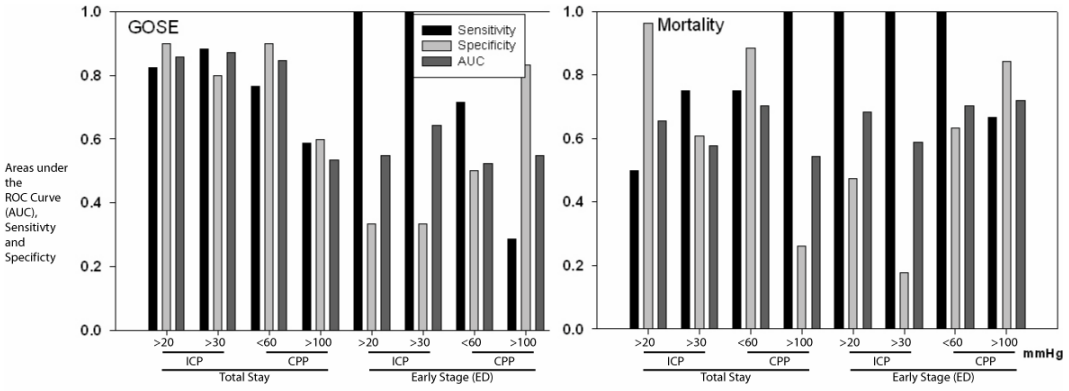
Sibel Kahraman, MD, Peter Hu, MS,CNE ,Yan Xiao, PhD, Richard P Dutton*, MD, Bizhan Aarabi*, MD, Deborah M Stein*, MD, Thomas M Scalea*, MD

American Association for the Surgery of Trauma Annual Meeting, October 2009

Background: Intracranial pressure (ICP) and cerebral perfusion pressure (CPP) measurements are the primary basis for the care of the severe traumatic brain injury (TBI) patients. We tested the accuracy of a pressure-time dose (PTD: mmHg*h) based on automated ICP and CPP data in predicting outcomes of severe TBI patients.

Methods: ICP and CPP data for 30 severe TBI patients were collected automatically at 6 sec intervals. PTDs of ICP and CPP over or under two different thresholds were calculated for early stage (Emergency Department stay: 3.4=/- 2.8 h) and total stay (4.6 +/- 2.6 d). Four outcomes (mortality, 3-month Extended Glasgow Outcome Scale -GOSE, discharge GCS and decompressive craniectomy) were used in assessing prediction value of PTDs.

Results: Total stay PTDs were strong predictors of GOSE and mortality (Fig.). In particular, early stage PTDs for ICP thresholds had 100% sensitivity but low specificity (17-47%). Total stay PTD of ICP>20mmHg correlated with discharge GCS (p=0.016), and PTD of ICP>30mmHg correlated with the need for decompressive craniectomy (p=0.03).



Conclusion: Dose-based scoring of continuous automated ICP and CPP recordings seems to be a strong predictor of outcomes in TBI. Direct management of dose-based scoring at early stages might be valuable in therapeutic decisions.

Real-time patient Vital Signs Data Registry for Trauma Patient Care

Dept of Anesthesiology University of Maryland
Richard Dutton MD, Peter Hu MS, CNE, Yan Xiao PhD, Dale Yeatts MD, Colin Mackenzie MD

American Society of Anesthesiologists Annual Meeting, October 2009

Introduction: Continuous display of patient physiological data is standard anesthesia practice; recording, retrieval and processing of such data is not. In time-critical, multi-tasking domains requiring life-saving interventions, documentation is sparse. We evaluated reliability of an automated vital signs collection system and tested proof of concept for 24x7 retrospective construction of events and prospective prediction of patient outcome

Methods: Real-time patient vital signs data feeds from monitors (GE-Marquette-Solar-7000/8000) were networked in a major trauma center to include 12 bed trauma resuscitation unit (TRU), 6 operating-rooms (OR), 9 post-anesthesia and 36 intensive care beds. Real-time vital signs waveforms, trends and alarms were compressed and transferred to a centralized server through the secured hospital intranet and archived. Custom processing and viewing programs were developed for patient data abstraction, artifact removal, 5-60 min time window averaging, and summary data output to both text and MS-Excel format (Figure 1). The server was interfaced with the CERNER to allow viewing of patient records and directly with Trauma Registry queries to provide over 100 patient-specific demographics and outcomes.

Results: During 12 months over 80 variables were collected including continuous electrocardiogram, oxygen saturation, end-tidal carbon dioxide (ECG/SpO2/CO2/Respiration) waveforms and numerical values every 6 seconds of heart rate, blood pressure, intracranial pressure, cerebral perfusion pressure, respiratory rate, temperature, (HR/BP/SpO2/ETCO2/ICP/CPP/RR/TEMP etc) at 240Hz. Data rates after compression averaged 76.4 KB/h for numerical and 12.3MB/h for waveforms. Over 20,000 days (64 patient-locations*365days= 23360 days) of over 8,000 patients vital signs were collected with system uptime > 99%. Based on patient admission and discharge timing from medical records, the system matched over 90% of patients and provided precise identification of timing and duration of hypotensive episodes, hypoxemic events, tracheal intubation (by ETCO2 waveforms). 100% of 384 TRU intubation data were captured in a 6-month data collection period. Specialized monitoring, e.g. of 27 Glasgow Coma Scale < 9 head-injured patients, validated continuous CPP as predicting mortality.

Conclusions: The trauma center wide system was reliable and provided a continuous record of events, because there were very few gaps in data collection. The system allowed automated documentation of patient care during time critical trauma patient reception and resuscitation, OR management and unusual events. Multivariable logistical regression of these data and linking with outcome could be used for Quality Management, teaching and health services research. Decision support algorithms and outcome predictions may be improved with such previously underutilized continuous vital signs data.

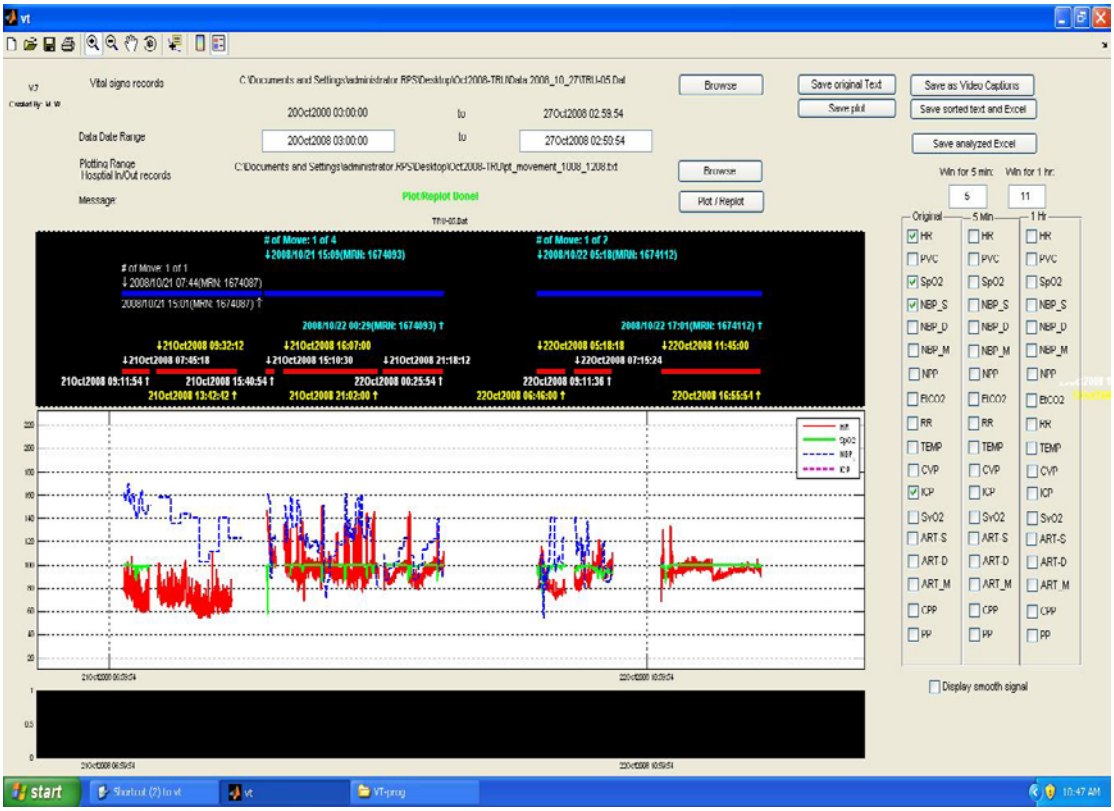


Fig1: VSDR interface

High Resolution ICP and CPP data better predict outcome of severe TBI

Richard P Dutton, M.D., M.B.A., Sibel Kahraman, M.D., Peter Hu, M.S., Yan Xiao, Ph.D. and Thomas Scalea, M.D.

American Society of Anesthesiologists Annual Meeting, October 2009

Background: Manual end-hour intracranial pressure (ICP) and cerebral perfusion pressure (CPP) documentation is the prevalent practice, even in dynamic patients. We assessed the impact of artifacts on accuracy and utility of real-time high resolution automated ICP and CPP recordings by comparing with manual documentation and evaluating its correlation with outcome in severe traumatic brain injury (TBI).

Methods: After IRB approval, 30 patients with severe TBI with admission Glasgow Coma Scale (GCS)<9, requiring ICP monitoring were included in the study. Real-time recordings of ICP and CPP were acquired automatically at 6 sec intervals via a Trauma Center-wide vital signs data collection network. Potential artifacts were cleaned by moving median with a window-size of 5 data points (30 sec). 5 min mean values were then calculated for 4.6±2.6 days. The extent and duration of ICP>20mmHg and CPP<60mmHg were calculated as pressure-time dose (PTD: mmHg*h) by using either automated (PTDa) or manual (PTDm) recordings. Bland-Altman plot was used to assess the agreement of PTDa and PTDm. Prediction values for in-hospital mortality and long term functional outcome (Extended Glasgow Outcome Scale; GOSE) were calculated using receiver operating characteristics (ROC) methods. Spearman rank correlation test was used to establish the correlation between PTD values and discharge GCS, length of ICU stay (LOS_ICU) and length of hospital stay (LOS_H).

Results: Thirty subjects (27 men, 3 women) yielded a total of 3296 hrs of data. Bland-Altman plots demonstrated general agreement between PTDa and PTDm with a mean bias of -3.8 for ICP (95% confidence interval: CI from -13.9 to 6.3) and -10.9 for CPP (95% CI from -0.2 to 22.1). PTDa and PTDm for ICP were significantly higher in patients with unfavorable outcome (GOSE≤4) than in patients with favorable outcome (GOSE>4) (p=0.0004 and p=0.01, respectively). However, for CPP where Bland-Altman plots showed the highest mean bias, PTDa but not PTDm showed significant difference between patients with favorable vs. unfavorable outcome (p=0.003 and p=0.053, respectively). Both PTDa and PTDm had high predictive power for functional outcome and in-hospital mortality (Table 1). Both PTDa and PTDm values for ICP and CPP were strongly correlated with LOS_ICU (p=0.009 and 0.007 vs. p=0.005 and 0.006, respectively), LOS_H (p=0.009 and 0.005 vs. p=0.001 and 0.005, respectively) and discharge GCS scores (p=0.008 and p=0.038 vs. p=0.042 and p=0.015, respectively).

Conclusion: PTD calculation of real time, high resolution ICP and CPP recording is less labor intensive than manual recording and showed better correlation with clinical outcomes. This technique should be the standard for future studies of severe TBI. Supported By W81XWH-07-2-0118

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Summary: 'Pressure*time' dose above critical thresholds of automatically captured high resolution ICP and CPP recordings shows high predictive power for mortality and long term functional outcome in severe TBI patients.

Continuous vital signs acquisition improves prehospital trauma triage

Ayan Sen, Peter Hu, Colin Mackenzie, Sean Jordan, Yan Xiao, Richard Dutton, Thomas Scalea.

16th World Congress of Disaster and Emergency Medicine, May 2009

Background

Vital signs data collected in pre-hospital care and recorded in trauma registries are often missing or unreliable as it is very difficult to record the dynamic changes while carrying out resuscitation and stabilization. The purpose of this paper is to test the hypothesis that analysis of continuous Vital signs (VS) improves data quality, and predicts life-saving interventions (LSI) better than use of retrospectively compiled Trauma Registry (TR) data.

Methods

After IRB approval, 6 EMS helicopters were equipped with a Vital Signs Data Recorder (VSDR) to capture continuous VS from the patient onto a handheld PDA. Pre-hospital LSI's (fluid bolus, CPR, drugs, intubation etc) and those carried out within 2 hours after arrival in the trauma resuscitation unit were considered outcome variables. VSDR and TR data were compared using Bland- Altman method. A multivariate analysis was performed to determine which VS variable best predicted LSI's using the values in the TR and the VSDR.

Results

Prehospital VSDR data were collected in 177 patients. There was significant difference between the highest and lowest heart rate, systolic blood pressure (SBP), oxygen saturation between the VSDR and the TR data ($p<0.001$). VSDR highest heart rate and lowest oxygen saturation recorded predicted LSI's while none of the TR vital signs did so in a multivariate model. SBP was not an independent predictor of LSI.

Conclusions

VSDR data increased the odds of predicting LSI's compared to the TR data. Using continuous vital signs in pre-hospital care may lead to development of better trauma prognostic models.

In-flight Vital Signs Blackbox for Trauma Care

Peter Hu MS CNE, Colin Mackenzie MD, Richard Dutton MD, Ayan Sen, MD, Yan Xiao PhD, Douglas Floccare MD MPH, Thomas Scalea MD

16th World Congress of Disaster and Emergency Medicine, May 2009

Introduction

Prompt and adequate medical response following an injury is the predominant goal in trauma care. Advances in telemedicine technology have made it easier to record patient vital signs (VS), events and life-saving interventions (LSI) in real-time in the hostile terrain of Emergency Medical Services (EMS) practice.

We report the results of vital signs Blackbox (VSB) used for aeromedical transfer to a major trauma center for collecting real-time vital-signs trends, waveforms and events.

Methods

The VSB uses a PDA(HP-iPAQ) with an embedded box (Inovamar Inc) to capture VS from a field patient VS monitor (Propaq 206). Real-time ECG, Heart Rate, SPO2, End-Tidal CO2 trends and waveforms are recorded continuously on a memory card (240hrs-2GB). Nine on-board LSI events were configured for rapid in-flight documentation.

Results

Six-Medevac helicopters were equipped with the VSB systems which have consistently captured waveforms(182Hz) and numerical data(1Hz) for 163 patients in six months period. The average duration of VS data was 25.9 minutes (+-5min). The data shows that patients were constantly monitored during the air transfer. Specific VS monitored during the transfer were ECG/ECG-HR/RR (95%), SpO2/SPO2-PR (87%), SBP/MBP/DBP (76%), CO2/ETCO2 (5%) for all cases. Pre-hospital care standards were assessed and captured waveforms and trends are being analyzed in association with patient outcomes.

Conclusions

A fully operational VSB system has been effective in collecting prehospital trauma VS.

Further mapping the pre-hospital physiologic trends with outcomes show promise in improve patient triage and standards of trauma care.

Supported by #W81XWH-05-0374, W81XWH-06-C-0034, and W81XWH-07-2-0118.

Video technologies in emergency health research in assessing quality of care: a study of trauma resuscitation milestones

Ayan Sen , Peter Hu, Colin Mackenzie, Yan Xiao, Richard Dutton

16th World Congress of Disaster and Emergency Medicine, May 2009

Background

Studies have demonstrated that trauma resuscitation times are predictive of patient outcome and increased delays were detrimental to patient care. Use of video technologies in emergency research is a novel way of ensuring quality of care and efficiency. We assessed resuscitation times, milestones and factors which influence golden hour trauma patient care in the emergency department (ED).

Methods

Following IRB approval, video recorded images were retrospectively analysed over a 4-week period, in 145 patients presenting with major trauma. Time to CT scan, conventional x-rays, Lodox Statscan, endotracheal intubation (ETI), insertion of chest tubes, central venous access was measured from time of patient admission. Multivariate analysis was performed to account for the influence of diurnal and on-call teams, patient census, Injury Severity Score (ISS) and the effect of patient GCS on time to resuscitation milestones. Statistical analysis was conducted using JMP SAS (SAS Institute, Cary, NC, USA)

Results

Our video analysis of trauma resuscitation showed 100% compliance with time to CT within 2 hrs in patients with GCS<=13. Reduced GCS and high ISS were strongly predictive of time to CT and ETI in a multivariate regression analysis ($p<0.001$). Use of Lodox Imaging, low ED census was associated with significantly reduced resuscitation times.

Conclusions

Video recording has the advantages of providing accurate times to interventions that are not hindered by poor documentation or the memory of those involved. It can be a useful tool in resuscitation quality evaluation and identify variances in process flow helping in addressing inefficiencies in emergency care.

Automated vital-sign recording identifies more critical episodes than chart abstraction

Peter Hu MS, CNE, Ayan Sen MD, Colin Mackenzie MD, FRCA, Yan, Xiao PhD, Sean Jordan EMT-B, Richard Dutton MD, MBA, Thomas Scalea, MD and Trauma Vital Signs Research Group (TVSG)

American Telemedicine Association Conference, April 2009

Introduction

Manual abstraction of clinical data (Vital-Signs VS), captured in the trauma registry (TR), has been the gold-standard used to develop pre-hospital triage protocols and outcome measures. We tested the accuracy of the TR against data collected by an automated VS data recorder (VSDR) in VS based critical episode identification.

Methods

Continuous pre-hospital VS (SBP/HR/SpO2) captured by a VSDR were assessed retrospectively by 3 independent raters (a physician, EMS provider and senior biomedical engineer). Inter-rater-reliability were calculated. Critical episodes of hypotension (SBP<90), tachycardia (HR>120) and hypoxia (SpO2<90%) identified in the VSDR data sets were compared to those captured by the TR using McNemar's test of significance of difference in proportions.

Results

VSDR data sets of 157 trauma patients transported by helicopters over a 6 month period were analyzed. The pre-hospital transfer time was 25.5 mins (Range:8-60 mins). Mean Injury Severity Score was 9.8 ± 7.9. Inter-rater-reliability was: 0.95(HR), 0.98(SBP), and 0.91(SpO2). Critical episodes identified in the VSDR datasets versus those in the TR datasets were 9 vs. 6 patients with hypotension ($p=.45$), 29 vs. 12 with tachycardia ($p<0.001$), and 18 vs. 4 with hypoxia ($p<0.01$). The resulting field Trauma and Injury Severity Scores (TRISS) were changed in 5% (7/157) of the patients when the VSDR data were used. Three of five patients with reduced TRISS using VSDR data required a life-saving intervention on arrival to the trauma center.

Conclusion

Automated VSDR systems provide both facilitation of patient care and accurate documentation. Such systems capture data with no interruption of pre-hospital care. In 157 patients, the VSDR dataset identified upto 3 times more pre-hospital critical episode than TR. In the future, streaming telemetry of such critical episode may enable more rapid and focused care at the time of trauma center arrival.

Support by USAMRMC, W81XWH-05-0374, W81XWH-06-C-0034, and W81XWH-07-2-0118

Can EMS Protocols be monitored remotely in pre hospital care of Traumatic Brain Injury (TBI)?

Colin Mackenzie MD, FRCA, Peter Hu MS, CNE Ayan Sen MD, Yan, Xiao PhD, Sean Jordan EMT-B, Richard Dutton MD, MBA, Thomas Scalea, MD.
American Telemedicine Association Conference, April 2009

What happens in pre-hospital management of TBI patients during Emergency Medical System (EMS) care remains anecdotal. National paramedic management protocols[1] require determination Glasgow Coma Scale (GCS); oxygenate to SpO2 95-100%; maintain blood pressure; intubation for GCS<=8, with end-tidal CO2 35+- 5 mmHg; treat hypoglycemia; apply cervical collar We tested a prototype system that collected and could transmit all objective TBI protocol management by continuous automated vital signs collection and limited run sheet input (collar, glucose).

Methods: Continuous real-time waveforms of electrocardiogram (ECG), SpO2, end-tidal carbon dioxide (ETCO2), non-invasive blood pressure (NIBP), and respiration were collected during helicopter EMS transport by interfacing a PDA (HP-iPAQ) based real-time data and event recording system with the pre-hospital vital signs monitoring device (Propaq model 206EL).
Results: Abnormalities (> 100/min) in ECG heart rate (HR) and SpO2 HR, oxygen saturation (< 95%) and NIBP (< 100 mmHg) were extracted. Among 64 patients, 16 had severe injury, 3 with TBI GCS<= 8, required intubation, one patient received glucose, all had cervical collars. NIBP was measured 3- 10 times. In 15 patients SpO2 was <95%. Among 3 TBI patients ETCO2 after intubation ranged from 23-48 mm Hg, respiration rate from 5-60/min, SpO2 <95% (2.5 minutes) and hyperventilation (> 7 minutes) and hypotension (> 10 minutes) exceeded TBI management guidelines. 2/3rds TBI patients died.

Conclusion: A single field SBP < 90 mmHg and SpO2 < 90% is reported[2] to double mortality from TBI. The critical duration and magnitude of hypotension, hypoxemia and hyperventilation were measured in TBI patients with our prototype automated data collection system and could be wirelessly transmitted The benefit is that medical situational awareness is available at all levels of command and in advance of trauma center arrival. The prototype demonstrated how the link can be made between real pre-hospital TBI care and patient outcomes.

Supported by W81-XWH-05-1-0374, W81-XWH-06-C-0034 and W81-XWH-07-2-0118

Statewide Real-Time In-Flight Trauma Patient Vital Signs Collection System

Peter Hu, MS, CNE[1], Colin Mackenzie, MD[1], Richard Dutton, MD[1],
Ayan, Sen, MD[1], Yan, Xiao PhD[1], Christopher Handley, MS, EMT-P[2], Danny Ho MS[1], Thomas Scalea, MD[1]
1. University of Maryland Shock Trauma Center 2. Maryland Institute for EMS Systems

Abstract: Continuous *recorded in-flight vital signs monitoring and life-saving interventions linked to outcomes may provide better understanding of pre-hospital triage, care management and patient responses during the 'golden hour' of trauma care. Evaluation of 157 patients' vital signs data collected from our statewide network has identified episodes of physiological decompensation which holds promise for creation of new triage algorithms and enhanced trauma center preparedness.*

Introduction: Current information about pre-hospital care of trauma patients is obtained from recall of the pre-hospital provider on arrival at the receiving hospital. Management of injuries detracts from the simultaneous documentation of events. Continuous collection of physiologic data and life saving intervention (LSI) events from pre-hospital care may provide insight into management and patient responses during the "golden hour" of trauma care. In conjunction with patient outcome data, such continuous physiological data collection system may provide the documentation which is currently lacking for evaluation of resuscitation interventions and stabilization [1] as well as other future telemedicine and decision support applications.

Methods: Statewide vital signs data collection (VSDC) network consists of three parts: 1) pre-hospital in-flight VSDC unit: a handheld PDA was used to capture VS from portable patient monitor (Propaq 206). Real-time waveform electrocardiogram (ECG), pulse oximeter oxygen saturation (SpO2), end-tidal carbon dioxide (ETCO2), heart rate (HR), non-invasive blood pressure (NIBP), and respiratory rate (RR) data are recorded continuously on a memory card. The card can store up to 100 cases (240 hrs, 1GB). Field LSI events (fluid infusion, cardiopulmonary resuscitation-CPR , drugs, tracheal intubation) were recorded on touch-screen PDA for in-flight documentation by paramedics. 2) Paramedic feedback: A secure website (www.vsdr.org) was used to gather input from the paramedics. Information collected includes fluid administration, LSI, lowest Glasgow Coma Scale (GCS) score, lowest NIBP, lowest HR and the likelihood of abdominal injury. 3) Pre-hospital VS database for mining and VS based prediction algorithm development. The data sets include continuous field VS, LSI, paramedic reported data all of which were linked with patient outcomes.

Results: Three statewide aeromedical bases (6 helicopters) were equipped with the VSDC system. The network was pilot-tested over a 6 month period. Data from 478 helicopter transfers to a major trauma center were collected. Continuous waveforms were captured at 182Hz (ECG) or 90Hz (SpO2, ETCO2) and numerical trend data at 1Hz. Following IRB approval, data from 157 patients was further evaluated. The mean (range) duration of pre-hospital transfer was 25.5 (8-60) min. EMS providers monitored up to 8 vital signs during the flight. In these 163 patients, VS parameters captured during the flight were: HR, 157 (100%); ETCO2, 5 (3 %); RR, 44 (28%); NIBP, 153 (97%), ECG waveforms, 145 (92%), SpO2 waveform, 156 (99%), ETCO2 6 (4 %) and respiratory waveform 17 (10%). Algorithms (Poincare plot, return mapping, outlier identification) for artifact reduction leading to clean filtered waveforms and trends have been developed. 22 (14%) patients have injury severity score greater than 15, indicate severe injury. The VS data indicates at least one episode of hypotension (SBP<90), hypoxia (SPO2<90%) and tachycardia (HR>120) in 7%, 13% and 23% of cases respectively. The processed VS data will be used to develop robust models to predict injury and interventions (tracheal intubation, blood transfusion, tube thoracostomy, etc). Paramedics feedback was gathered for 78% of the cases. The rest of the pre-hospital events were collected from patient chart and trauma registry review. All patient outcomes have been linked with the pre-hospital VS data set**.**

Discussion: The VSDC network demonstrated operational feasibility to continuously collect physiologic data from the in-flight trauma patient. Operational testing and analyses of continuous VS data collection will allow evaluation of pre-hospital triage, improved prognostic trauma scores, and other applications including telemedicine and emergency medical services quality management. Availability of such pre-hospital VS with novel triage and prediction model would enhance receiving trauma center's readiness and coordination.

Supported in part by DoD-TATRC#W81XWH-05-0374, W81XWH-06-C-0034, W81XWH-07-2-0118 and State Maryland Police Aviation Command.

Reference

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Continuous Prehospital Vital Signs Record Identifies Increased Abnormalities/Predicts Interventions

Ayan Sen MD, Peter Hu MS, CNE, Colin Mackenzie MD, FRCA, Sean Jordan EMT-B, Richard Dutton MD, MBA.

American Society of Anesthesiologists Annual Conference, October 2008

Background: In the time-critical phase of pre-hospital trauma care, changes in vital signs (VS) need to be recorded during resuscitation and stabilization. We tested the hypothesis that continuous, automated collection of field VS data identifies more episodes of abnormalities and improves prediction of life-saving interventions (LSI) like endotracheal intubation, tube thoracotomy, blood transfusion etc than the manual method as reported in the trauma registry (TR).

Methods: Continuous pre-hospital VS (SBP, HR, SpO2) captured by a pre-hospital VS data recorder (VSDR) were assessed retrospectively by 3 independent raters. Inter-rater reliability (IRR) was assessed by Pearson r. Ranges and standard deviations (SD) of values from continuous VS (highest/lowest/ first minute/last minute of collection) were compared to TR VS by paired t-test. Episodes of SBP [<90; <110], HR [>100; 120] and SpO2 [<95; <90] identified in the continuous VS record were compared to TR data by McNemars test . Changes in field Trauma Injury Severity Score (TRISS) and admission TRISS were computed using different VS sources. Probability of abnormal VS predicting a LSI on arrival to trauma center was assessed by univariate analysis and plotting the ROC (Receiver-Operator Curve). Statistical Analysis was conducted using JMP7 (SAS Institute, Cary, NC).

Results: The records of 148 patients collected over a 6 month period were analyzed. The pre-hospital transfer time was 25.5 mins (Range 8- 60 mins). ISS was 9.8 + SD 7.9. IRR was: HR(r = 0.91-0.99), SBP (r=0.97-0.98), DBP= (r=0.95-0.99) and SpO2(r=0.84-0.97) captured in the first minute, last minute and of the highest and lowest VS values. Manually collected prehospital VS were significantly different from automated VS ($p<0.001$). Increased numbers of episodes of abnormal VS ($p<0.001$) were captured by automated VS.[table1]LSI in the pre-hospital phase or on arrival to trauma center were better predicted using combination of abnormal VS from continuous record (area under ROC curve 0.55-0.65) in comparison to TR VS (0.49-0.52). The numbers of patients whose field and admission TRISS were different based on automated versus manually collected of VS were 7 (5%) and 5 (3%), respectively, for the 148 patients analyzed, all due to the additional hypotensive episodes captured by the automated method (p=0.45). Majority (60%, n=3/5) of those with worse scores needed life-saving interventions after arrival to the trauma center.

Conclusions : Prediction of interventions, long-term outcomes and prognostic modeling are improved with continuous automated capture of VS. Major differences in detection of hypoxemia, hypotension and HR increase suggest that prediction possibilities of pre-hospital VS and scores (TRISS) are being missed when TR with intermittent VS data are used.

Challenges in developing real-time in-flight patient vital-signs data collection system

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American Telemedicine Association Annual Meeting, April 2008

Introduction: Developing a reliable real-time in-flight patient vital-signs data collection system (VSDC) presents many challenges, but is necessary to understand field management issues. We report the challenges and some solutions for design and deployment of such system.

Methods: VSDC uses a PDA (HP-iPAQ) to collect real-time patient vital signs (VS) data from a commonly used VS monitor (Propaq-Encore206EL). VSDC can store up to 350 hours (1 GB) of continuous patient VS waveform (ECG at181Hz, SPO2/ETCO2 at 90Hz) and numerical trended data (HR/SpO2/ETCO2/NIBP/Temp at 1Hz) for evaluation, data analysis and data mining.

Results: Challenges: Observed unreliability of consumer grade PDA under high-speed live serial (RS232) data collection; high maintenance; interface design issues; short battery life; PDA required protective field packaging; multi-site field system deployment required effective communication with the field care provides. Solutions: A data interface box was built to improve serial data communication; a real-time error detection, self recovery algorithm corrected the frequent occurrence of PDA power disruptions during field operation; patient monitor connection status, SPO2 and BP value display, and events marker buttons simplified the user interface; a secure web interface for information dissemination, patient information collection, remote training, and user feedback facilitated multi-site deployment. The two VSDC systems in Medevac helicopters which transfer patients to a major trauma hospital have collected 116 in-flight patient VS data sets with the average case length of 25.9 minutes (1.38 MB filesize).

Discussion: Efforts to build a reliable and user-friendly data collection device is essential to successful system deployment. Remote user training, support, and feedback through the web interface were well received. Great support and instant feedback from the State police aviation division made the rapid system updates possible. Also, the PDA battery life remains a challenge for long-term service free operation.

Supported by DoD-TATRC#W81XWH-05-0374, SBIR-W81XWH-06-C-0034 and State Maryland Police Aviation Command.

Lesson Learned: Developing In-Flight Patient Vital-Signs Data Collection Network

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5th Annual Innovations in the Surgical Environment Conference, June 2008

Background:

Developing a reliable real-time in-flight patient vital-signs data collection system (VSDC) presents many challenges, but is necessary to understand field management issues. We report the challenges and some solutions for design and deployment of such a system.

Methods:

VSDC uses a PDA (HP-iPAQ) to collect real-time patient vital signs (VS) data from a commonly used VS monitor (Propaq-Encore206EL). VSDC can store up to 350 hours (1 GB) of continuous patient VS waveform (ECG at 182 Hz, SpO2/ETCO2 at 90Hz) and numerical trended data (HR/SpO2/ETCO2/NIBP/Temp at 1 Hz) for evaluation, data analysis and data mining.

Results:

Challenges: Observed unreliability of consumer grade PDA under high-speed live serial (RS232) data collection; high maintenance; interface design issues; short battery life; PDA required protective field packaging; multi-site field system deployment required effective communication with the field care providers. Solutions: A data interface box was built to improve serial data communication; a real-time error detection, self recovery algorithm corrected the frequent occurrence of PDA power disruptions during field operations; patient monitor connection status, SpO2 and BP value display, and events marker buttons simplified the user interface; a secure web interface for information dissemination, patient information collection, remote training, and user feedback facilitated multi-site deployment. The three VSDC systems in Medevac helicopters which transfer patients tot a major trauma hospital have collected 157 in-flight patient VS data sets with the average case length of 25.9 minutes (1.38 MB filesize).

Discussion:

Efforts to build a reliable and user-friendly data collection device is essential to successful system deployment. Remote user training, support and feedback through the web interface were well received. Great support and instant feedback from the STATE police aviation division made the rapid system updates possible. Also, the PDA battery life remains a challenge for long-term service free operation.

Summary of Staff, Roles and Percent Effort by Project/Sub-project

STAFF MEMBER	ROLE	% EFFORT (%FTE)
Thomas Scalea	PI	6.30
Lisa Gettings	Administrator	0
Karen Murdock	Project Manager	55
Colin Mackenzie	Sub-Project PI; Vital Signs study	40
Peter Hu	Co-Investigator	41.5
Yan Xiao (up to 9/11/09)	Technical Support	1.5
Steven Seebode	Technical Support	57.4
Matthew Woodford	Post-doctoral Fellow	100
Yu-Wei Chang	GRA	100
Eric Lund	IT Application Engineer	95.0
Reeba Thomas	Coordinator; Vital Signs study	37.2
Deborah Stein	Sub-project PI; Cytokine study	8.4
Bizhan Aarabi	Co-Investigator	2
Richard Dutton	Co-Investigator	8.8
Allison Lindell	Coordinator; Cytokines study	2.1
Kaspar Keledjian	Cytokine technician	0
Robert Rosenthal	Sub-project PI; Animal model	20.4
Gary Fiskum	Co-Investigator	25
Karen Volpini	Database Management	48.9
Madeline Mitrou	Research Nurse	36.6
Yawei Wang	Research Nurse	47.3
Margaret Mensa	Research Nurse	11.2
Marianne Hattan	Research Nurse	90
Krysta Taylor	Research Nurse	29.1
Keri Volpini	Research Assistant	30
Christine Wade-Mariani	Research Assistant	10
Charles Simpson	Research Assistant	76.5
Tondeleyo Gonzalez	Research Assistant	87.5
Carrie Sauer	Research Assistant	90
Olga Kolesnik	Research Assistant	67.5
Sean Jordan	Research Assistant	44.5
Sara Wade	Research Assistant	90
David Prakash	Research Assistant	63.6
Scott Berry	Research Assistant	100
Jonathan Gooch	Research Assistant	90

Cris Imle	Physical Therapist	5.2
Kristina Clem	Data Entry	44.1
Joe Kufera	Statistician	25
Gordon Smith	Epidemiologist	19.6
Julie Hazleton	Technician	50
Wei Xiong	GRA	100
Anantharanga Prithviraj	GRA	100
Keng-Hao Liu	GRA	100
Susanna Scafidi	Co-Investigator	5
Rao Gulliapalli	Co-Investigator	8.7
Matt Lissauer	Co-Investigator	8.5
Jiachen Zhuo	Post-doctoral Fellow	53.3

*Includes expenditures through 9/30/09